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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,345	03/20/2001	Derek David Smith	180.0002 0102	2898

26813 7590 05/20/2002

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,345

Applicant(s)

SMITH ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 27 and 28 are cancelled; and 21-26 and 29-53 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 21-26 and 29-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121. It is note that the following restriction requirement is applied to the pending claims 21-26 and 29-53 because the claims that are not included hereon are cancelled.

- I. Claims 21-26 and 29-47, drawn to methods of inhibiting CGRP binding to CGRP receptor, are classified in class 530, subclass 300, class 435, subclass 7.1 and 7.21 and class 514, subclass 2⁺.
- II. Claims 48-50, drawn to a method of identifying CGRP antagonist, are classified in class 435, subclass 7.1 and 7.21 and class 530, subclass 300.
- III. Claims 51-53, drawn to a method of identifying CGRP receptor, are classified in class 435, subclass 7.1 and 7.21 and class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Invention I, II and III are directed to different and/or distinct methods of using CGRP antagonist and CGRP receptor, a method of inhibiting CGRP binding to CGRP receptor, a method of identifying CGRP antagonist, and a method of identifying CGRP receptor, respectively. These methods differ with respect to method steps, end-products, targets, and ingredients; therefore, each method is patentably distinct.

Additional Election Under 35 USC 121

Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed peptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

(i) If Group I is elected, applicant is required to elect:

- 1) one polypeptide from SEQ ID NO. 1, 2, 6-17-23 (see Claims 31, 34 and 35);

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- 2) one antagonist peptide from Claim 36; elect a R^1 group from Claim 41;
- 3) a chemical substituent for each $R^4 - R^8$ in Claim 43;
- 4) a definitive carbon atom in the Claimed ring structure to which the selected R^1 group is covalently attached and a Y chemical group from Claim 45;
- 5) one antagonist peptide or polypeptide from Claim 46;
- 6) a chemical group from Claim 47; and in the same claim, a definitive carbon atom in the claimed ring structure from each said chemical group to which the selected R^1 group is covalently attached; and one chemical group for "X" in the said each ring from "C" or "N".

Note that each chemical substitution results in different or distinct structure and mode of chemical reaction.

(ii) If Group I is elected, applicant is required to elect every required species in order to meet the same restriction/election requirement since Independent claim Claim 48 discloses the identical general formula to that of Claim 29 that is independent claim of Invention I.

(iii) If Group III is elected, applicant is required for an election (see the reason stated in the election requirement for Invention II) since Claim 48 (an independent claim) discloses the identical general formula disclosed in Claim 51 (an independent claim) is the same as that of Claim 29 (an independent claim) of Invention I and because both Invention II and III use CGRP antagonist(s) that is/are derived from the structure of the general formula in spite of their being directed to the distinct process with distinct targets for analysis.

Because reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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A telephone call was made to Ann Muetting on May 15, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is required that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for

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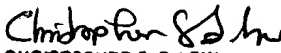
the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



SWL

May 15, 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600